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| APPLICATION NO.                                                                                                         | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------------------------------------------------------------------------------------------------------|-------------|----------------------|---------------------|------------------|
| 09/995,949                                                                                                              | 11/28/2001  | Anandan Palani       | CN01365K            | 2864             |
| 24265                                                                                                                   | 7590        | 10/06/2003           | EXAMINER            |                  |
| SCHERING-PLOUGH CORPORATION<br>PATENT DEPARTMENT (K-6-1, 1990)<br>2000 GALLOPING HILL ROAD<br>KENILWORTH, NJ 07033-0530 |             |                      | SAEED, KAMAL A      |                  |
|                                                                                                                         |             |                      | ART UNIT            | PAPER NUMBER     |
|                                                                                                                         |             |                      | 1626                |                  |

DATE MAILED: 10/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 09/995,949             | PALANI ET AL.       |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Kamal A Saeed          | 1626                |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 13,15-19 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☒ Claim(s) 1-12,14,20,22 and 23 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

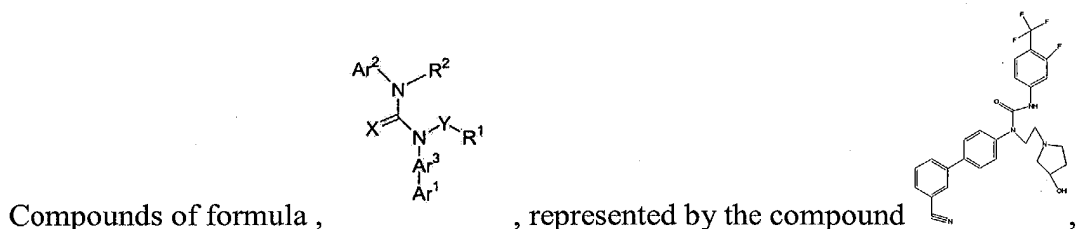
- |                                                                                              |                                                                             |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____                                    |

### DETAILED ACTION

Claims 1 – 24 are pending in this application.

### Status of the Claims

The scope of the elected invention, described in the Office Action mailed on March 19, 2003, has been modified as follows:



*1-(3'-Cyano-biphenyl-4-yl)-3-(3-fluoro-4-trifluoromethyl-phenyl)-1-[2-(3-hydroxy-pyrrolidin-1-yl)-ethyl]-urea*

, wherein: **X** is O; **Y**, is a single bond or

(C<sub>1</sub>-C<sub>3</sub>)alkylene; **R**<sup>1</sup> is optionally substituted pyrrolidine or piperidine group; **R**<sup>2</sup> is H or (C<sub>1</sub>-C<sub>6</sub>)alkyl; **R**<sup>3</sup> is independently H, or nonsubstituted or halosubstituted -(C<sub>1</sub>-C<sub>6</sub>)alkyl, -(C<sub>3</sub>-C<sub>7</sub>)cycloalkyl, -(C<sub>1</sub>-C<sub>6</sub>)alkoxy, -(C<sub>3</sub>-C<sub>7</sub>)cycloalkyl-(C<sub>1</sub>-C<sub>6</sub>)alkyl, -(C<sub>1</sub>-C<sub>6</sub>)alkoxy-(C<sub>1</sub>-C<sub>6</sub>)alkylene, aryl or aralkyl; **R**<sup>4</sup> is as defined; **R**<sup>5</sup> is independently H, or nonsubstituted or halosubstituted -(C<sub>1</sub>-C<sub>6</sub>)alkyl, -(C<sub>3</sub>-C<sub>7</sub>)cycloalkyl, -(C<sub>1</sub>-C<sub>6</sub>)alkoxy, -(C<sub>3</sub>-C<sub>7</sub>)cycloalkyl-(C<sub>1</sub>-C<sub>6</sub>)alkyl, -(C<sub>1</sub>-C<sub>6</sub>)alkoxy-(C<sub>1</sub>-C<sub>6</sub>)alkylene, aryl or aralkyl; **Ar**<sup>1</sup> is aryl group having a cyano group as a substituent; **Ar**<sup>2</sup> is aryl group; and **Ar**<sup>3</sup> is an aryl group.

As a result of the election and the corresponding compounds identified supra, the remaining subject matter of claims 1-11, 12, 14, 20, 22 and 23 ( in part) and claims 13, 15-19, and 21 directed to method of use as stated previously (in Office Actions mailed March 19, 2003) are withdrawn from further consideration pursuant to 37 CFR 1.142 (b) as being drawn to non-elected inventions.

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The compounds, which are withdrawn from consideration as being non elected subject matter, differ materially in structure and composition from the compounds of the elected invention. The withdrawn compounds contain varying functional groups which differ from those of the elected invention such diazine, morpholine, thiazine group etc. This recognized chemical diversity of the functional groups can be seen by various classification of these functional groups in the US classification system i.e. class 544 subclass 106+ (morpholine), class 544 subclass 3+ (thiazine), class 544 subclass 224+ (diazine) etc. Therefore, the compounds, which are withdrawn from consideration as being for non elected subject matter, differ materially in structure and composition and have been restricted properly as a reference, which anticipated, but the elected subject matter would not even render obvious the non-elected subject matter.

**Applicant's claim involves more than one independent or distinct invention** . Under 35 U.S.C. 121, the claims may be restricted and the examination limited to the restricted invention. Accordingly, restriction as has been presented in this application is proper. The requirement to restrict is repeated and made Final.

### ***Objections***

Claims 1-11, 12, 14, 20, 22 and 23 are objected to for containing non-elected subject matter. Claims 1-11, 12, 14, 20, 22 and 23 presented solely to the elected invention as identified supra, would appear allowable over the prior art of record.

Therefore **THIS ACTION IS MADE FINAL** . Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136 (a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

### ***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kamal Saeed whose telephone number is (703) 308-4592. The examiner can normally be reached on Monday-Friday from 8:00 AM – 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308 4537. The unofficial fax phone for this group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate the Header (upper right) "Official" for papers that are to be entered into the file, and " Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

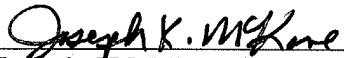
Communication via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive

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data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-2286.

Kamal Saeed, Ph.D  
September 24, 2003

  
\_\_\_\_\_  
Joseph K McKane,  
Supervisory Patent Examiner  
Art Unit 1626, Group 1626  
Technology Center 1